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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,922	11/03/2003	Johanna Bergmann	830006-2000	5900
20999	7590	02/07/2006	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			EMCH, GREGORY S	
			ART UNIT	PAPER NUMBER
			1649	
DATE MAILED: 02/07/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/700,922	<b>Applicant(s)</b> BERGMANN ET AL.	
	<b>Examiner</b> Gregory S. Emch	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group XXXIII, claims 8 and 9, in the communication dated 03 January 2006 is acknowledged. Applicant argues that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Group XXXIII would provide the relevant art for the remaining Groups and that the European Patent Office concluded that the claims were restricted to one invention.

Applicant's argument has been fully considered and is found to be partially persuasive. First, the proceedings of the European Patent Office are irrelevant to U.S. Patent prosecution. Second, Applicant's attention is directed to MPEP 808.02 which states that "Where the related inventions as claimed are shown to be distinct under the criteria of MPEP 806.05 (c-i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof; (B) A separate status in the art when they are classifiable together; (C) A different field of search."

As set forth in the Restriction requirement of 04 November 2005, Group I is classified in class 435, subclass 91.1; Groups II-IV are classified in class 536, subclass 23.1; Groups V-XVII are classified in class 536, subclass 24.1; Groups VXVIII-XX are classified in class 530, subclass 324; Groups XXI-XXIII are classified in class 435, subclass 7.1; Groups XXIV-XXVI are classified in class 435, subclass 7.5; Groups

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VXVII-XXIX are classified in class 424, subclass 139.1; Groups XXX-XXXII are classified in class 530, subclass 300; Groups XXXIII-XXXV are classified in class 424, subclass 130.1; and Groups XXXVI-XXXVIII are classified in class 530, subclass 387.1.

The separate classification established for the Groups demonstrates that they have attained recognition in the art as separate subjects for inventive effort, and also a separate field of search. However, the Examiner agrees that it would not be an undue burden to examine Groups XXXIII-XXXV, since the Groups are within the same class and subclass. Thus, the Restriction requirement will be modified such that Groups XXXIII-XXXV are examined together. Hence, claims 1-7 and 10 are withdrawn from further consideration, as being drawn to nonelected inventions. Furthermore, the Restriction requirement is hereby made FINAL. Currently, claims 8 and 9, drawn to methods of passive vaccination, wherein the vaccine includes antibodies against the proteins of amino acids 68-79 of SEQ ID NO: 2, amino acids 20-51 of SEQ ID NO: 6, and amino acids 33-44 of SEQ ID NO: 15 are under consideration.

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

This application is claiming the benefit of prior-filed nonprovisional application No. 09/242,449 under 35 U.S.C. 120, 121, or 365(c). Copendency between the current

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application and the prior application is required. Since the applications are not copending, the benefit claim to the prior-filed nonprovisional application is improper.

MPEP Chapter 201.11 states: "There are six conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120, 121, or 365(c) or under 35 U.S.C. 119(e)...(B) With respect to claiming benefit under 35 U.S.C. 120, 121, or 365(c), the later-filed application must be copending with the prior application or with an application similarly entitled to the benefit of the filing date of the prior application."

In the instant case, Applicant claims priority as a continuation to U.S. Patent Application No. 09/242,449, which was abandoned on 10/02/2003. The instant Application was filed on 11/03/2003, thus no co-pendency was established with the earlier Application to which priority was claimed. Therefore, the benefit of the earlier filing date is denied, and thus, the effective filing date for the instant Application is 11/03/2003.

#### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

### ***Claim Objections***

Claims 8 and 9 are objected to because of the following informalities: The claims depend on non-elected base claims. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They are replete with grammatical and idiomatic errors. Regarding claim 8, the phrase "see also" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It appears that Applicant is attempting to incorporate by reference in the claims. However, it is unclear what should be included from the references.

Furthermore, the claims are drawn to methods of passive vaccination to prevent and stop initiation and progression of Alzheimer's disease, wherein the vaccine includes antibodies against the proteins of amino acids 68-79 of SEQ ID NO: 2, amino acids 20-51 of SEQ ID NO: 6, and amino acids 33-44 of SEQ ID NO: 15. In the instant application, SEQ ID NOs: 2 and 15 are nucleic acid molecules and SEQ ID NO: 6 is

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only 40 amino acids long. Thus, it is unclear what is encompassed by Applicant's invention.

Claims 8 and 9 are also rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a selection step, an administration step, and a conclusion step.

Appropriate corrections are required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/07850 to Bergmann et al.

The claims are drawn to methods of passive vaccination to prevent and stop initiation and progression of Alzheimer's disease, other associated diseases, and other diseases in humans wherein the vaccine includes antibodies against the proteins of amino acids 68-79 of SEQ ID NO: 2, amino acids 20-51 of SEQ ID NO: 6, and amino acids 33-44 of SEQ ID NO: 15. The Examiner assumes that Applicant intended the sequences recited by the claims to be drawn to antibodies against the proteins of amino

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acids 68-79 of SEQ ID NO: 3, amino acids 20-51 of SEQ ID NO: 4, and amino acids 33-44 of SEQ ID NO: 5.

Accordingly, the '850 document teaches polypeptides with amino acid sequences, which are 100% identical to Applicant's SEQ ID NOs: 3 and 5 and 93.9% identical to Applicant's SEQ ID NO: 4 (1 deletion). The '850 document also teaches proteins, especially antibodies, or antibody fragments, that are capable of binding amino acids 67-79 of the instant SEQ ID NO: 3 and amino acids 32-44 of the instant SEQ ID NO: 5 (pp.14-15). Since the claimed residues are completely within the residues taught by the '850 document, the instantly claimed antibodies are anticipated. Further, the '850 document contemplates methods of treating and preventing Alzheimer's disease by providing an individual in need of such treatment, an effective amount of the antibodies or fragments thereof (p.15 and 39). Additionally, the treatment may be prophylactic and the disorders may be other diseases in humans (pp.17-18), such as the Alzheimer's related condition Down syndrome. Also, the immunotherapy can be in the form of a passive vaccine and can be humanized (p.39). Thus, since the document teaches all the elements of the claims, claims 8 and 9 are anticipated by WO 98/07850 to Bergmann et al.

### ***Conclusion***

No claims are allowed.



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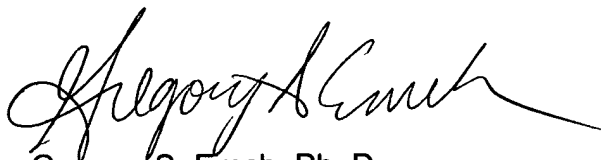
The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Gregory S. Emch, Art Unit 1649.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 8:30AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1649  
February 3, 2006



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